

REMARKS/ARGUMENTS

Claims 5, 7, 10-13, 15-22 are currently pending in this application. Claims 16-22 are canceled in the present reply. Claims 5, 7, 10 and 15 are currently amended. These claims have been canceled or amended without prejudice to, or disclaimer of, the subject matter thereof. Applicant reserves the right to file continuing applications directed to the subject matter of any claim canceled or amended for any reason.

The amendments to claims 5, 7, 10 and 15 place the application in better condition for examination. It is submitted that no new matter has been introduced by these amendments with support found throughout the specification as filed. By these amendments, Applicant does not acquiesce to the propriety of the Office's rejections and does not disclaim any subject matter to which Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 USPQ.2d 1865 (US 1997).

I. 35 USC §102 Rejections

Claims 5, 7, 10, 12, 13, 15-20 and 22 stand rejected under 35 USC § 102(b) as allegedly anticipated by USPN 6,057,367 ("Stamler"). July 2, 2009 Office Action ("OA"), page 2. Applicants respectfully disagree with these rejections and the Office's positions regarding the same.

In order to support an anticipation rejection under 35 U.S.C. § 102, the Office must illustrate that each and every element of a claimed invention was disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). A claimed invention is anticipated only when it is "known to the art in the detail of the claim." *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of the claim be shown in a single prior art reference, the limitations must be "arranged as in the claim." *Id.* Stamler does not teach or disclose every element of the pending claims.

As amended, the pending claims require (i) administering a composition comprising active isomers or active and inactive isomers in an effective amount wherein the effective amount is based at least in part on the ratio of active to inactive isomers in the composition or (ii) administering a composition comprising active and inactive ingredients wherein said active ingredient consists essentially of alpha-methyl-L-

methionine-S-sulfoximine (α -Me-MSO) or alpha-ethyl-L-methionine-S-sulfoximine (α -Et-MSO). Stamler does not disclose administering a composition comprising active isomers or active and inactive isomers in an effective amount wherein the effective amount is based at least in part on the ratio of active to inactive isomers in the composition. Moreover, Stamler does not disclose administering a composition comprising active and inactive ingredients wherein said active ingredient consists essentially of alpha-methyl-L-methionine-S-sulfoximine (α -Me-MSO) or alpha-ethyl-L-methionine-S-sulfoximine (α -Et-MSO). Instead, Stamler states,

[t]he selective inhibitors of microbial gamma-glutamylcysteine synthetase include, e.g., α -alkyl-S-alkyl-homocysteine sulfoximines (especially the corresponding DL,RS compounds and the L,S-diastereomers) where the α -alkyl contains 2 to 8 carbon atoms and the S-alkyl contains 1 to 10 carbon atoms.

Stamler, Col. 15, ll. 7-12 (emphasis added). Additionally, the Office states that “[t]he instantly claimed compounds are a subset of the compounds of Stamler et al. wherein the S-alkyl group is a methyl group.” OA, page 4. This statement is incorrect. Stamler recites a compound wherein the α -alkyl group can be 2-8 carbons. As pending, the current claims recite an α -alkyl group of 1-8 carbons wherein the S-alkyl group is a methyl group or an α -alkyl group of 1 or 2 carbons wherein the S-alkyl group is a methyl group. Thus, the presently claimed compounds are not a subset of those described by Stamler.

Based on all for the foregoing reasons, Applicants respectfully request that the Examiner reconsider and withdraw the pending rejections of claims 5, 7, 10-13 and 15 under 35 U.S.C. § 102(b).

II. 35 USC § 103 Rejections

Claims 11 and 21 stand rejected under 35 USC § 103(a) as allegedly unpatentable over Stamler in view of the Merck Manual of Diagnosis and Therapy, Seventeenth Edition (“Merck”). OA, page 5. Applicants respectfully disagree with these rejections and the Office’s positions regarding the same.

To maintain a proper rejection under 35 U.S.C. § 103, the Office must meet four conditions to establish a *prima facie* case of obviousness. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

Claim 21 has been canceled. Claim 11 depends from independent claim 5 or 10. As stated above in relation to Stamler, pending independent claims 5 and 10 recite (i) administering a composition comprising active isomers or active and inactive isomers in an effective amount wherein the effective amount is based at least in part on the ratio of active to inactive isomers in the composition or (ii) administering a composition comprising active and inactive ingredients wherein said active ingredient consists essentially of alpha-methyl-L-methionine-S-sulfoximine (α -Me-MSO) or alpha-ethyl-L-methionine-S-sulfoximine (α -Et-MSO). Stamler does not teach or suggest these limitations. Merck does not remedy these deficiencies of Stamler.

Based on the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the pending rejection of claim 11 under 35 U.S.C. § 103.

III. Non-Statutory Obviousness-Type Double Patenting Rejections

Claims 5, 7, 10, 12, 13, 15-20 and 22 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-6 of Stamler. OA, page 7. Applicants respectfully disagree with these rejections and the Office's positions regarding the same.

As stated above in relation to the rejections based on Stamler and Stamler and Merck, the pending claims recite (i) administering a composition comprising active isomers or active and inactive isomers in an effective amount wherein the effective amount is based at least in part on the ratio of active to inactive isomers in the composition or (ii) administering a composition comprising active and inactive ingredients wherein said active ingredient consists essentially of alpha-methyl-L-methionine-S-sulfoximine (α -Me-MSO) or alpha-ethyl-L-methionine-S-sulfoximine (α -Et-MSO). Claims 1-6 of Stamler do not teach or suggest these limitations.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the pending rejections of claims 5, 7, 10, 12, 13 and 15 on the ground of nonstatutory obviousness-type double patenting.

CONCLUSION

Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 503207. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully Submitted,

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